IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appellant: Abraham J. Domb and Joseph S. Wolnerman

Serial No.: 10/083,413 Art Unit: 1655

Filed: February 27, 2002 Examiner: Flood, Michele C.

For: *ABSORBABLE SOLID COMPOSITIONS FOR TOPICAL TREATMENT OF ORAL MUCOSAL DISORDERS*

Mail Stop Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPEAL BRIEF

Sir:

This is an appeal from the final rejection of claims 1-4, 6-12, 14-17, 19-26, and 38 in the Office Action mailed March 10, 2006, in the above-identified patent application. A Notice of Appeal was filed on June 12, 2006. The Commissioner is hereby authorized to charge $250.00, the fee for the filing of this Appeal Brief for a small entity, to Deposit Account No. 50-3129. Submitted with this Appeal Brief is a Petition for Extension of Time, along with the required fee for a small entity, to extend the period for response two months, to and including October 19, 2006. The Commissioner is hereby authorized to charge $225.00, the fee for a two month extension of time for a small entity, to Deposit Account No. 50-3129. It is believed that no additional fee is required with this submission. However, should an additional fee be required, the Commissioner is hereby authorized to charge the fee to Deposit Account No. 50-3129.

U.S.S.N. 10/083,413
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APPEAL BRIEF

(1) REAL PARTY IN INTEREST

The real party in interest of this application is Axiomedic, Inc.

(2) RELATED APPEALS AND INTERFERENCES

This case was previously on appeal. An appeal brief was filed on June 27, 2005. In response, the Examiner reopened prosecution and an office action was mailed on September 23, 2005.

(3) STATUS OF CLAIMS

Claims 1-4, 6-12, 14-17, 19-26, and 38 are pending. Claims 5, 13, 18, and 27-37 have been cancelled. Claims 1-4, 6-12, 14-17, 19-26, and 38 are on appeal. The text of each claim on appeal, as pending, is set forth in an Appendix to this Appeal Brief.

(4) STATUS OF AMENDMENTS

An amendment and response after a final rejection was filed via electronic transmission on August 21, 2006. A substitute amendment and response after final was filed on September 21, 2006. In the final Office Action mailed on March 10, 2006, the Examiner indicated that deletion of the term "homeopathic agents" from claim 1 would overcome the enablement rejection. Claim 1 was amended in such a manner in the amendment and response after final filed on September 21, 2006. The claims were also amended to correct typographical and grammatical errors and to over overcome the objection under 37 C.F.R. 1.75(c) as requested by the Examiner. An appendix sets forth the claims on appeal.

(5) SUMMARY OF CLAIMED SUBJECT MATTER

Independent claim 1 is directed to a solid, self-bioadhesive composition for topical application that adheres to oral mucosal tissue comprising: (a) a therapeutically effective amount of at least one herbal active agent wherein the herbal agent is selected from the group consisting of bioactive herbs, herbal extracts, tinctures, essential oils, and mixtures thereof, and (b) a pharmaceutically acceptable solid bioadhesive carrier, comprising a mucoadhesive synthetic polycarboxylic acid polymer, in an amount from about 40 to 99 percent based on the weight of the whole composition in a form suitable for administration and adhesion to the oral mucosa (page 10, lines 21-27; page 11, lines 12-18; and page 12, lines 18-21). The composition may be in the form of a disk having a diameter of between 2 and 15 mm and a thickness of between 0.4 and 2.3, preferably having a diameter of between 5 and 11 mm, a thickness of between 1 and 2 mm (dependent claims 2 and 3; page 27, lines 9-11), and a surface area of 0.4 to 3 cm^2 (claim 38; page 13, lines 27-29). The composition adheres to the oral mucosal tissue for at least 30 minutes, preferably at least one hour (dependent claims 2 and 3; page 22, lines 15-18).

The herbal active agent is selected from the group consisting of anti-inflammatory, analgesic, antiaching, anesthetic, antimicrobial, antifungal, antiseptic, antiviral, antibiotic, antiparasite agents, and combinations thereof (dependent claim 4, page 17, lines 7-9). Examples of herbal and homeopathic agents include Echinacea, Salvia officinalis, Hypericum, Myrrh, Camphoria, Uncaria, menthol, Plantago, Baptisia, Calendula, Phytolacca, Catechu black, Coneflower, Krameria, Tsuga, grape fruit seed extract, Rosmarinus, Styrax, Crataegus,

Glycerrhiza, Angelica, Kramerica, Matricaria, Mallow, Propolis, Sage, berberine from hydrastis canadensis L., plant family Berberidaceae, gentian from the gentianaceae family of plants for the treatment of fungal infections, monoterpenes of three unsaturations, Taraxacum extract, Lonicera flower extract, Scutellaria root extract, Gardenia fruit extract, Pulsatilla root extract, Pueraria root extract, Radix gentianae Longdancao antifungal agent, and combinations thereof (dependent claim 6; page 17, lines 20-31). The herbal active agent may also be an essential oil selected from the group consisting of citronella oil, lemon oil, citron oil, pomelo peel oil, cedarwood oil, juniper berries oil, lemon basil oil, Rosmarinus officinalis oil, cinnamon oil, cajeput oil, eucalyptus oil, fennel oil, geranium oil, girofle oil, lavendar oil, clove oil, spearmint oil, myrtle oil, oregano oil, pine oil, rosemary oil, sarriette oil, thyme oil, tea-tree oil, and combinations thereof (dependent claims 7-11 and 19; page 17, lines 9-13 and page 19, line 29 to page 14, line 19). The compositions may also contain a salt (dependent claims 12, 14, 20, and 21) or a non-herbal active agent (dependent claims 15-18; page 10, lines 2-7). The composition may contain one or more excipients (claims 24-25; page 13, lines 20-26)

The bioadhesive carrier may be a mixture of cross-linked synthetic polycarboxylic acid polymers (claim 22; page 12, lines 8-21), alone or in combination with cellulosic polymers, polysaccharides, starch derivatives, acrylic acid polymers, PVA, PEO, and combinations thereof. The solid bioadhesive carrier can also be a polyacrylic acid polymers crosslinked with a polymer selected from the group consisting of polyalkenyl polyether, carboxymethylceullose, hydroxymethylcellulose, and mixtures thereof. (claims 23 and 26; page 12, lines 8-21).

(6) GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The issues presented on appeal are:

(1) whether claims 1-4, 6, 15-17, 22-24, 26, 27, and 38 are novel as required by 35 U.S.C. § 102(b) over U.S. Patent No. 4,772,470 to Inoue *et al.* ("Inoue");

(2) whether claims 1-3, 15-17, 22-24, 26, 27, and 38 are novel as required by 35 U.S.C. § 102(b) over U.S. Patent No. 4,226,848 to Nagai *et al.* ("Nagai"); and.

(2) whether claims 1-4, 6-12, 15-17, 19, 22-27, and 38 are non-obvious as required by 35 U.S.C. § 103(a) over U.S. Patent No. Inoue in view of U.S. Patent No. 5,939,050 to Iyer *et* al. ("Iyer") and U.S. Patent No. 6,197,305 to Friedman *et al.* ("Friedman") with evidence provided by The Illustrated Encyclopedia of Essential Oils by Lawless ("Lawless").

(7) ARGUMENT

(i) Rejections Under 35 U.S.C. § 102

Legal Standard

For a rejection of claims to be properly founded under 35 U.S.C. § 102, it must be established that a prior art reference discloses each and every element of the claims. *Hybritech Inc. v Monoclonal Antibodies Inc.*, 231 U.S.P.Q. 81 (Fed. Cir. 1986); *Scripps Clinic & Research Found v. Genentech Inc.*, 18 U.S.P.Q.2d 1001 (Fed. Cir. 1991). The Federal Circuit held in *Scripps*, 18 U.S.P .Q.2d at 1010:

> Invalidity for anticipation requires that all of the elements and limitations of the claim are found within a single prior art reference. . . There must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention.

A reference that fails to disclose even one limitation will not be found to anticipate, even if the missing limitation could be discoverable through further experimentation. As the Federal Circuit held in Scripps, *Id.*:

> [A] finding of anticipation requires that all aspects of the claimed invention were already described in a single reference: a finding that is not supportable if it is necessary to prove facts beyond those disclosed in the reference in order to meet the claim limitations. The role of extrinsic evidence is to educate the decision maker to what the reference meant to persons of ordinary skill in the field of the invention, not to fill in the gaps in the reference.

For a prior art reference to anticipate a claim, it must enable a person skilled in the art to practice the invention. The Federal Circuit held that "a §102(b) reference must sufficiently describe the claimed invention to have placed the public in possession of it. . . [E]ven if the claimed invention is disclosed in a printed publication, that disclosure will not suffice as prior art if it was not enabling." *Paperless Accounting Inc v Bay Area Rapid Transit Sys.*, 231 U.S.P.Q. 649, 653 (Fed. Cir. 1986).

Analysis

a. U.S. Patent No. 4,772,470 to Inoue et al. ("Inoue")

Claim 1, 4, 6, 15-17, and 23-24 are not anticipated by U.S. Patent No. 4,772,470 to Inoue *et al.* ("Inoue")

Inoue describes an oral bandage comprising a soft adhesive film comprising a mixture of a polycarboxylic acid and/or a polycarboxylic acid anhydride and a vinyl acetate polymer and having incorporated therein a topical drug (abstract). Inoue does not disclose a composition comprising a bioadhesive carrier in an amount from about 40 to 99 percent based *on the weight of the whole composition* as required by claim 1. Inoue discloses that the *dissolution ratio* of the polycarboxylic acid is 40% by weight or less. Dissolution ratio is not the same as weight percent of the total composition. The dissolution ratio is the ratio of polycarobxylic acid that dissolved in water from a polycarboxylic acid-polyvinyl acetate film divided by the amount of the polycarboxylic acid contained in the film (col. 4, lines 35-44). The dissolution ratio does not take into account the amount of active agent and/or excipients present in the composition. The dissolution ratio provides information regarding compatibility of the polycarboxylic acid and the polyvinyl acetate, not weight percent of the film in the final composition. In the examples, the polycarboxylic acid-polyvinyl acetate is laminated to a support film. No information is given regarding the weight of the support film, thus the weight percent of the bioadhesive material cannot be determined. Inoue does not disclose each and every element of claim 1. Accordingly, claim 1, and the claims dependent thereon, are novel over Inoue.

Claim 2, 3, and 38 are not anticipated by Inoue

The compositions described in Inoue are films. Inoue does not disclose or suggest disks prepared by compression molding having the diameters and thicknesses specified in claims 2 and 3. Further, Inoue does not disclose or suggest a composition wherein the surface area is from about 0.4 to 3 cm^2. Accordingly, claims 2, 3, and 38 are novel over Inoue.

Claims 22 and 26 are not anticipated by Inoue

Claim 22 is dependent from claim 1 and specifies that the solid bioadhesive carrier is selected from the group consisting of crosslinked synthetic polycarboxylic acid polymers. Claim 26 depends from claim 22 and specifies that the solid bioadhesive carrier is selected from polyacrylic acid polymers crosslinked with a polymer selected from the group consisting of polyalkenyl polyether, carboxymethylceullose, hydroxymethylcellulose, and mixtures thereof. Nagai does not disclose or suggest a composition wherein the solid bioadhesive carrier is one or more crosslinked synthetic polycarboxylic acid polymers. The compositions described in Inoue contain a mixture of a polycarboxylic acid and/or a polycarboxylic acid anhydride and a vinyl acetate polymer. There is no disclosure in Inoue that the polymers are crosslinked. Accordingly, claims 22 and 26 are novel over Inoue.

The rejection of claim 27 appears to be in error since claim 27 was previously canceled.

b. U.S. Patent No. 4,226,848 to Nagai et al. ("Nagai")

Claims 1-3, 23-24, 26, 27, and 38 are not anticipated by Nagai

Nagai describes pharmaceutical preparations comprising a water-swellable and mucosa-adhesive polymeric matrix comprising about 50% to about 95% by weight of a cellulose ether and about 50 to about 5% by weight of a homo or copolymer of acrylic acid and dispersed therein a pharmaceutically effective amount of medicament (abstract). Suitable medicaments are listed on at col. 5, line 58 to col. 6, line 17. None of the drugs described in Nagai are bioactive herbs, herbal extracts, tinctures, essential oils, and/or mixtures thereof as required by claim 1. It is important to note that the Examiner did not reject claims 4 and 6-11 which specify particular herbal active agents. Accordingly, claims 1-3 are novel over Nagai.

Claims 15-17 are not anticipated by Nagai

Claim 15 is dependent on claim 1 and specifies that the composition further comprises a non-herbal active agent. Claims 16-17 specify particular non-herbal active agents which can be used in the claimed composition in combination with one or more herbal active agents. As discussed above, Nagai does not disclose or suggest compositions containing bioactive herbs, herbal extracts, tinctures, essential oils, and/or mixtures thereof as required by claim 1. Accordingly, claims 15-17 are novel over Nagai.

Claims 22 and 26 are not anticipated by Nagai

Claim 22 is dependent from claim 1 and specifies that the solid bioadhesive carrier is selected from the group consisting of crosslinked synthetic polycarboxylic acid polymers. Claim

26 depends from claim 22 and specifies that the solid bioadhesive carrier is selected from polyacrylic acid polymers crosslinked with a polymer selected from the group consisting of polyalkenyl polyether, carboxymethylceullose, hydroxymethylcellulose, and mixtures thereof. Nagai does not disclose or suggest a composition wherein the solid bioadhesive carrier is one or more crosslinked synthetic polycarboxylic acid polymers. The compositions described in Nagai contain 50 to 95% by weight of a cellulose ether and 50% to 5% of a homo- or copolymer of acrylic acid or a pharmaceutically acceptable salt thereof. There is not disclosure that the polymers are crosslinked. Accordingly, claims 22 and 26 are novel over Nagai.

The rejection of claim 27 appears to be in error since claim 27 was previously canceled.

(ii) Rejections Under 35 U.S.C. § 103

Legal Standard

References relied upon to support a rejection under 35 U.S.C. § 103 must provide an enabling disclosure, i.e., "they must place the claimed invention in the possession of the public." *Application of Payne*, 606 F.2d 303, 314, 203 U.S.P.Q. 245 (C.C.P.A. 1979); *see Beckman Instruments, Inc. v. LKB Produkter AB*, 892 F.2d 1547, 13 U.S.P.Q.2d 1301 (Fed. Cir. 1989). A publication that is insufficient as a matter of law to constitute an enabling reference may still be relied upon, but only for what it discloses. *See Reading & Bates Constr. Co. v. Baker Energy Resources Corp.*, 748 F.2d 645, 651-652, 223 U.S.P.Q. 1168 (Fed. Cir. 1984); *Symbol Technologies, Inc. v. Opticon, Inc.*, 935 F.2d 1569 (Fed. Cir. 1991).

"Focusing on the obviousness of substitutions and differences, instead of on the invention as a whole, is a legally improper way to simplify the often difficult determination of obviousness." *Gillette Co. v. S.C. Johnson & Sons, Inc.*, 919 F.2d 720, 724, 16 U.S.P.Q.2d 1923 (Fed. Cir. 1990); *see Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1383, 231 U.S.P.Q. 81, 93 (Fed. Cir. 1986). "One cannot use hindsight reconstruction to pick and choose among isolated disclosures on the prior art to deprecate the claimed invention." *In re Fine*, 837 F.2d 1071, 1075 (Fed. Cir. 1988).

The prior art must provide one of ordinary skill in the art with the motivation to make the proposed modifications needed to arrive at the claimed invention. *See In re Geiger* , 815 F.2d 686, 2 U.S.P.Q.2d 1276 (Fed. Cir. 1987); *In re Lalu and Foulletier*, 747 F.2d 703, 705, 223 U.S.P.Q. 1257, 1258 (Fed. Cir. 1984). Claims for an invention are not *prima facie* obvious if the primary references do not suggest all elements of the claimed invention and the prior art does not suggest the modifications that would bring the primary references into conformity with the application claims. *In re Fritch*, 23 U.S.P.Q.2d, 1780 (Fed. Cir. 1992). *In re Laskowski*, 871 F.2d 115 (Fed. Cir. 1989). This is not possible when the claimed invention achieves more than what any or all of the prior art references allegedly suggest, expressly or by reasonable implication.

Obviousness is determined as follows. "A proper analysis under § 103 requires, *inter alia,* consideration of two factors: (1) whether the prior art would have suggested to those of ordinary skill in the art that they should make the claimed composition or device, or carry out the

claimed process; and (2) whether the prior art would also have revealed that in so making or carrying out, those of ordinary skill would have a reasonable expectation of success." *Noelle v. Lederman*, 355 F.3d 1343, 69 USPQ2d 1508 (Fed. Cir. 2004) Both a suggestion to make a claimed composition or process and a reasonable expectation of success must be founded in the prior art, not in the applicant's disclosure. *Velander v. Garner*, 348 F.3d 1359, 68 USPQ2d 1769 (Fed. Cir. 2003); *see also In re Dow Chem. Co.*, 837 F.2d 469, 473 (Fed. Cir. 1988).

Analysis

Claims 1, 22-24, and 26 are not obvious over Inoue in view of Iyer and Friedman with evidence by Lawless

a. Inoue

As discussed above, Inoue does not disclose a composition comprising a bioadhesive carrier in an amount from about 40 to 99 percent based *on the weight of the whole composition* as required by claim 1.

b. U.S. Patent No. 5,939,050 to Iyer et al. ("Iyer")

Iyer describes antimicrobial compositions comprising at least two antimicrobial agents which exhibit reduced MIC values relative to the MIC values for the agents making up the combination when measured alone (abstract). Iyer does not disclose a solid, self-bioadhesive tablet formulation for topical application that adheres to the oral mucosal tissue. As noted at col. 7, lines 16-27 and lines 53-61, these formulations are oral rinses, mouth washes or cleansers.

c. U.S. Patent No. 6,197,305 to Friedman et al. ("Friedman")

Friedman describes an anti-fungal composition containing (a) an extract of botanical materials, the botanical materials including material from Echinacea species and Propolis; and (b) an essential oil (abstract). The composition can be in the form of a mouthwash, a suppository, or a cream. Friedman does not disclose a solid, self-bioadhesive composition for topical application that adheres to the oral mucosal tissue. The formulations are not bioadhesive. Ingredients such as those at col. 7 are either hydrophobic (such as beeswax) or liquid (glycerin and oil) or contain detergent (such as sodium lauryl sulfate). Table 3 describes a liquid mouthwash formulation, not a solid. Table 4 describes an oral gel primarily of polyethylene glycol, which is not bioadhesive alone. Tables 5 and 6 describe hydrophobic skin cream.

d. Lawless, The Illustrated Encyclopedia of Essential Oils ("Lawless")

Lawless describes that the essential oil of lemon contains approximately 70% limonene as well as sabinene, myrcene, and pinenes (page 120). Lawless does not disclose a self-bioadhesive composition for topical application that adheres to oral mucosal tissue, nor a homeopathic amount.

e. The references alone, or in combination, do not disclose each and every element of the claims

In order to establish a *prima facie* case of obviousness, the references, alone or in combination, must disclose each and every element of the claims (*In re Royka*, 490 F.2d 981, 180 U.S.P.Q. 580 (CCPA 1974) "[t]o establish *prima facie* obviousness of a claimed invention,

all the claim limitations must be taught or suggested by the prior art.."). As discussed above, Inoue does not disclose a composition comprising a bioadhesive carrier in an amount from about 40 to 99 percent based *on the weight of the whole composition* as required by claim 1. The remaining references do not disclose or suggest the elements missing from Inoue. Further, none of the references disclose or suggest a composition in the form of a compressed tablet as specified in claims 2 and 3. Finally, in order to establish a *prima facie* case of obviousness, the prior art must provide one of ordinary skill in the art with the motivation to make the proposed modifications needed to arrive at the claimed invention. One of ordinary skill in the art would not have been motivated to combine the non-bioadhesive formulations of Iyer, Fiedman, and Lawless with the formulation of Inoue to arrive at the claimed compositions. Accordingly claims 1 and 22-26 are not obvious over Inoue in view of Iyer and Friedman with evidence by Lawless.

Claims 2, 3, and 38 are not obvious over Inoue in view of Iyer and Friedman with evidence by Lawless

As discussed above, Inoue does not disclose the bioadhesive composition of claim 1 in the form of compressed tablet having the diameters and thickness specified in claims 2 and 3. Inoue does not disclose the composition of claim 1 having a surface area from about 0.4 to 3 cm^2. In order to establish a *prima facie* case of obviousness, the references, alone or in combination, must disclose each and every element of the claims. Iyer, Friedman and/or

Lawless do not disclose the elements missing from Inoue. Accordingly, claims 2, 3, and 38 are not obvious over Inoue in view of Iyer and Friedman with evidence by Lawless.

Claims 7-12 and 19 are not obvious over Inoue in view of Iyer and Friedman with evidence by Lawless

As discussed above, Inoue does not disclose or suggest the bioadhesive composition of claim 1. Inoue does not disclose or suggest a composition wherein the herbal active agent is an essential oil (claim 7-8), at least one monoterpene with three unsaturations (claim 9), or an essential oil which is a natural or synthetic mixture consisting of limonene and at least one myrcene, a-pinene, b-pinene, and sabinene characterized in that at least 60% by weight of the mixture is limonene (claim 10). Inoue does not disclose or suggest a composition comprising $MgBr_2$, NaCl, KCl, and mixtures thereof (claim 12) nor carnallite or a salt of carnallite (claim 13).

Iyer, Friedman, and Lawless do not provide the elements missing from Inoue. Iyer discloses antimicrobial compositions comprising at least two antimicrobial agents which exhibit reduced MIC values relative to the MIC values for the agents making up the combination when measured alone. Friedman describes an anti-fungal composition containing (a) an extract of botanical materials, the botanical materials including material from Echinacea species and Propolis; and (b) an essential oil. Lawless describes that the essential oil of lemon contains approximately 70% limonene as well as sabinene, myrcene, and pinenes. The fact that these references disclose some of the compounds specified in claims 7-12 is immaterial. In order to

establish a *prima facie* case of obviousness, the prior art must provide one of ordinary skill in the art with the motivation to make the proposed modifications needed to arrive at the claimed invention. None of the references cited disclose a composition comprising a bioadhesive carrier in an amount from about 40 to 99 percent based *on the weight of the whole composition* as required by claim 1. One of ordinary skill in the art would not have been motivated to combine the non-bioadhesive formulations of Iyer, Fiedman, and Lawless with the formulation of Inoue to arrive at the claimed compositions. Accordingly, claims 7-12 and 19 are not obvious over Inoue in view of Iyer, Friedman, and Lawless.

(8) SUMMARY AND CONCLUSION

Inoue does not disclose a bioadhesive composition comprising a pharmaceutically acceptable solid bioadhesive carrier, comprising a mucoadhesive synthetic polycarboxylic acid polymer, in an amount from about 40 to 99 percent based on the weight of the whole composition in a form suitable for administration and adhesion to the oral mucosa. Inoue disclose the dissolution ratio of a polycarboxylic acid polymer in a polycarboxylic acid-polyvinyl acetate film. Dissolution ratio is not the same as weight composition of the total composition.

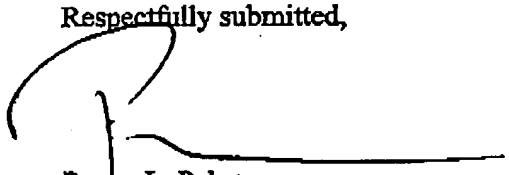
Nagai does not disclose a solid, bioadhesive composition comprising at least one herbal active agent.

Inoue does not disclose a bioadhesive composition comprising a pharmaceutically acceptable solid bioadhesive carrier, comprising a mucoadhesive synthetic polycarboxylic acid polymer, in an amount from about 40 to 99 percent based on the weight of the whole

composition in a form suitable for administration and adhesion to the oral mucosa. Iyer, Friendman, and/or Lawless do not disclose the elements missing from Inoue. Accordingly, the claims are not obvious over these references.

For the foregoing reasons, Appellant submits that claims 1-4, 6-12, 14-17, 19-26, and 38 are patentable.

Respectfully submitted,



Patrea L. Pabst.
Reg. No. 31,284

Date: October 19, 2006

PABST PATENT GROUP LLP
400 Colony Square, Suite 1200
1201 Peachtree Street
Atlanta, Georgia 30361
(404) 879-2155
(404) 879-2160 (Facsimile)

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Claims Appendix: Claims On Appeal

1. A solid, self-bioadhesive composition for topical application that adheres to oral mucosal tissue comprising:

(a) a therapeutically effective amount of at least one herbal active agent wherein the herbal active agent is selected from the group consisting of bioactive herbs, herbal extracts, tinctures, essential oils, and mixtures thereof, and

(b) a pharmaceutically acceptable solid bioadhesive carrier, comprising a mucoadhesive synthetic polycarboxylic acid polymer, in an amount from about 40 to 99 percent based on the weight of the whole composition in a form suitable for administration and adhesion to the oral mucosa.

2. The solid composition of claim 1 wherein the composition is in the form of a disc of 2 to 15 mm diameter and 0.4 to 2.3 mm thick that adheres to the oral mucosal tissue for at least 30 minutes.

3. The solid composition of claim 1 where the composition is in the form of a disc 5 to 11 mm in diameter and 1 to 2 mm thick with tissues adherence of at least 1 hour.

4. The composition of claim 1 wherein the herbal active agent is selected from the group consisting of anti-inflammatory, analgesic, antiaching, anesthetic, antimicrobial, antifungal, antiseptic, antiviral, antibiotic, antiparasite agents, and combinations thereof.

6. The composition of claim 1 wherein the herbal agent is selected from the group consisting of Echinacea, Salvia officinalis, Hypericum, Myrrh, Camphoria, Uncaria, menthol, Plantago, Baptisia, Calendula, Phytolacca, Catechu black, Coneflower, Krameria, Tsuga, grape fruit seed extract, Rosmarinus, Styrax, Crataegus, Glycerrhiza, Angelica, Kramerica, Matricaria, Mallow, Propolis, Sage, berberine from hydrastis canadensis L., plant family Berberidaceae,

gentian from the gentianaceae family of plants for the treatment of fungal infections, monoterpenes of three unsaturations, Taraxacum extract, Lonicera flower extract, Scutellaria root extract, Gardenia fruit extract, Pulsatilla root extract, Pueraria root extract, Radix gentianae Longdancao antifungal agent, and combinations thereof.

7. The composition of claim 1, wherein the herbal active agent is an essential oil selected from the group consisting of citronella oil, lemon oil, citron oil, pomelo peel oil, cedarwood oil, juniper berries oil, lemon basil oil, Rosmarinus officinalis oil, cinnamon oil, cajeput oil, eucalyptus oil, fennel oil, geranium oil, girofle oil, lavendar oil, clove oil, spearmint oil, myrtle oil, oregano oil, pine oil, rosemary oil, sarriette oil, thyme oil, tea-tree oil, and combinations thereof.

8. The composition of claim 7, wherein the herbal active agent is an essential oil selected from the group consisting of cinnamon oil, tea-tree oil, citronella oil, and combinations thereof.

9. The composition of claim 6, wherein the herbal active agent comprises at least one monoterpene with three unsaturations.

10. The composition of claim 1, wherein the herbal active agent is an essential oil and the essential oil is a natural or synthetic mixture consisting of limonene and at least one myrcene, a-pinene, b-pinene, and sabinene characterized in that at least 60% by weight of the mixture is limonene.

11. The composition of claim 9, wherein the monoterpene with three unsaturations is a citrus oil selected from the group consisting of lemon oil, pomelo oil, citron oil, and combinations thereof.

12. The composition of claim 1, further comprising a salt selected from the group consisting of $MgBr_2$, NaCl, KCl and mixtures thereof.

14. The composition of claim 1 further comprising Carnallite or a salt of Carnallite.

15. The composition of claim 1, further comprising a non-herbal active agent.

16. The composition of claim 15, wherein the non-herbal active agent is selected from the group consisting of at least one base or acid-addition salt of procaine, lidocaine, prilocaine, mepivacaine, dyclonine, dibucaine, benzocain e, chloroprocaine, tetracaine, bupivacaine, and etidocaine.

17. The composition of claim 15, wherein the non-herbal active agent is selected from the group consisting of at least one base or acid-addition salt of dexamethasone, triamcinolone, hydrocortisone, amphotericine B, nystatin, itraconazole, chlorhexidine, quaternary ammonium salts, parabens, and dextranase enzymes.

19. The composition of claim 1, wherein the active agent consists of a mixture of natural or synthetic monoterpenes with three unsaturations selected from the group consisting of limonene, myrcene, pinenes, sabinene, and terpinene.

20. The composition of claim 15 comprising a citron oil and Carnallite salt at a ratio between 1:10 and 1:1.

21. The composition of claim 15 comprising a citron oil and Carnallite salt at a ratio between 1:10 and 1:1 and a local anesthetic selected from the group consisting of lidocaine, benzocaine, and bupivecaine.

22. The composition of claim 1, wherein the solid bioadhesive carrier is selected from the group consisting of crosslinked synthetic polycarboxylic acid polymers and mixtures thereof.

23. The composition of claim 1 wherein the polymer is a copolymer of one or more polymers selected from the group consisting of hydroxypropyl cellulose, hydroxypropyl methylcellulose, hydroxyethylcellulose, carboxymethyl cellulose, dextran, arabinogalactan, pullulan, guar-gum, hyaluronic acid, pectins, starch derivatives, acrylic acid polymers, polymer of acrylic acid esters, polymers of vinyl alcohols, alkoxy polymers, polyethylene oxide polymers, polyethers and combinations thereof.

24. (previously presented) The composition of claim 1 further comprising an excipient selected from the group consisting of fillers, tableting excipients, lubricants, enhancers, flavors, taste-masking agents, pH controlling compounds, dyes, stabilizers, enzyme inhibitors, and mixtures thereof.

25. The composition of claim 24 wherein the enhancers are selected from the group consisting of bile acids and limonene.

26. The composition of claim 22 wherein the solid bioadhesive carrier is selected from polyacrylic acid polymers ~~lightly~~ crosslinked with a polymer selected from the group consisting of polyalkenyl polyether, carboxymethylceullose, hydroxymethylcellulose, and mixtures thereof.

38. The composition of claim 1, wherein the composition has a surface area ranging from about 0.4 to about 3 cm^2.

Evidence Appendix

No evidence is submitted with this Appeal Brief

Related Proceedings Appendix

This case was previously on appeal. An appeal brief was filed on June 27, 2005. In response, the Examiner reopened prosecution and an office action was mailed on September 23, 2005. Applicants filed an amendment and response to this office action on December 23, 2005. A final office action was mailed on March 10, 2006. This brief is in response to the final action mailed on March 10, 2006.